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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,860	03/31/2005	Hiromu Ohnogi	1422-0670PUS1	1481
2292	7590	09/25/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			CLARK, AMY LYNN	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/529,860

Applicant(s)

OHNOGI ET AL.

Examiner

Amy L. Clark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 7-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/31/05, 3/20/06, 4/21/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, Claims 5 and 6 and Applicant's election of Umbelliferae and the plant species *Angelica keiskei* koidz. in the reply filed on 14 August 2006 is acknowledged. The traversal is on the ground(s) that the invention is improperly divided into eight groups and that at least the claims of Groups III and IV should be joined because these Groups each relate to a single general inventive concept under PCT Rule 13.1 due to the fact that under PCT Rule 13.2 they each share the same corresponding special technical feature. Applicant further argues that a "special technical feature" is one that defines a contribution that the invention makes over the prior art. Applicant further argues that in the instant case, the special technical feature shared among Groups III and IV is 'a compound represented by Formula A.' Applicant further argues that this feature is sufficient to confer unity of invention to Groups III and IV in the present application. Applicant further argues that the Examiner has put forward no prior art that removes this feature of the invention from consideration as a special technical feature and, therefore, claims 7-8 and 9, at least, should be joined. Applicant further argues that at least the claims of Groups V, VI, VII and VIII should be joined because these Groups share a special technical feature, i.e. 'culturing hybridoma obtained by using HuO9 cells or a substrain thereof, or any one of cell strains therefrom with contact of a test substance; and measuring an amount of BMP in a culture medium obtained in the step (a).' Applicants submit that this feature is sufficient to confer unity of invention to Groups V, VI, VII and VIII (page

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40, at lines 1-4, the specification states "the amount of BMP production in the cells can be stably measured for the first time by using the cell strains of the present invention among various cells for BMP production") and Applicant further argues that this feature makes a contribution over the prior art. Applicant further argues that the Examiner has put forward no prior art that removes this feature of the invention from consideration as a special technical feature and that claims 10-13 should be joined.

Applicant states that the Examiner has required Applicants to elect one species of the invention of Group II, which the Examiner describes as generic and that the Examiner directs Applicants to elect a compound, derivative or salt from claim 7 of Group II (See Office Action, page 7). Applicant further states that claim 7 is not included in Group II and no elected compounds are encompassed within the claims of Group II and, therefore, Applicants assume that they are to elect a plant family and a plant species encompassed by claims 5 and 6 and elect the plant family Umbelliferae and the plant species *Angelica keiskei* koidz and that claims 1-6 read on the elected species. Applicants state that this election of species serves as a starting pointing for search and examination only and that upon indication of allowable subject matter for the elected species, the Examiner must expand the search to include other non-elected species with the intent to finding a generic claim ultimately allowable.

This is not found persuasive for the reasons set forth below and for the reasons set forth in the previous Office Action.

Restriction is required under 35 U.S.C. 121 and 372.

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This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, drawn to a therapeutic agent or prophylactic agent for a disease requiring promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the therapeutic agent or prophylactic agent comprises as an effective ingredient a processed product derived from a plant selected from the following (a) to (c): (a) a processed product derived from a plant belonging to Umbelliferae; (b) a processed product derived from a plant belonging to Liliaceae; and (c) a processed product derived from a plant belonging to Compositae.

Group II, claims 5 and 6, drawn to a food, beverage or feed for promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the food, beverage or feed comprises a processed product derived from a plant selected from the following (a) to (c): (a) a processed product derived from a plant belonging to Umbelliferae; (b) a processed product derived from a plant belonging to Liliaceae; and (c) a processed product derived from a plant belonging to Compositae.

Group III, claims 7 and 8, drawn to a therapeutic agent or prophylactic agent for a disease requiring promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the therapeutic agent or prophylactic agent comprises as an effective ingredient a compound represented by the following formula (A): a derivative thereof or a salt thereof.

Group IV, claim 9, drawn to a food, beverage or feed for promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the food, beverage or feed comprises the compound represented by the formula (A) as defined in claim 7, a derivative thereof or a salt thereof.

Group V, claim 10, drawn to a method for measuring an enhancing action for bone morphogenetic protein production, characterized in that the method comprises the following steps of: (a) culturing hybridoma obtained by using HuO9 cells or a substrain thereof, or any one of cell strains therefrom with contact of a test substance; and (b) measuring an amount of BMP in a culture medium obtained in the step (a) as an index for an enhancing action for BMP production of the test substance.

Group VI, claim 11, drawn to a method for screening a substance having an enhancing action for bone morphogenetic protein production, characterized in that the method comprises the following steps of: (a) culturing hybridoma obtained by using HuO9 cells

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or a substrain thereof, or any one of cell strains therefrom with contact of a test substance; and (b) measuring an amount of BMP in a culture medium obtained in the step (a) wherein the test substance is determined to have an enhancing action for BMP production when the amount of BMP is larger than that of a case where the cells are cultured without contact of the test substance or with contact of a control substance having an enhancing action for BMP production.

Group VII, claim 12, drawn to a method for preparing a substance having an enhancing action for bone morphogenetic protein production, characterized in that the method comprises the following steps of: (a) obtaining a substance having an enhancing action for bone morphogenetic protein production; and (b) measuring the enhancing action for bone morphogenetic protein production of the substance obtained in the step (a) using the measurement method as defined in claim 10.

Group VIII, claim 13, drawn to a method for preparing a substance having an enhancing action for bone morphogenetic protein production, characterized in that the method comprises the following steps of: (a) culturing hybridoma obtained by using HuO9 cells or a substrain thereof, or any one of cell strains therefrom with contact of a test substance; and (b) measuring an amount of BMP in a culture medium obtained in the step (a), wherein the test substance is determined to have an enhancing action for BMP production when the amount of BMP is larger than that of a case where the cells are cultured without contact of the test substance or with contact of a control substance having an enhancing action for BMP production, thereby giving the test substance as a substance having an enhancing action for BMP production.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is drawn to a therapeutic agent or prophylactic agent for a disease requiring promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the therapeutic agent or prophylactic agent comprises as an effective ingredient a processed product derived from a plant selected from the following (a) to (c): (a) a processed product derived from a plant belonging to Umbelliferae; (b) a processed product derived from a plant belonging to Liliaceae; and (c) a processed product derived from a plant belonging to Compositae, whereas the special technical feature of Group II is drawn to a food,

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beverage or feed for promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the food, beverage or feed comprises a processed product derived from a plant selected from the following (a) to (c): (a) a processed product derived from a plant belonging to Umbelliferae; (b) a processed product derived from a plant belonging to Liliaceae; and (c) a processed product derived from a plant belonging to Compositae and a search for a therapeutic agent is not required for a search for a food, beverage or feed. The special technical feature of Group III is drawn to a therapeutic agent or prophylactic agent for a disease requiring promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the therapeutic agent or prophylactic agent comprises as an effective ingredient a compound represented by the following formula (A): a derivative thereof or a salt thereof and the special technical feature of Group IV is drawn to a food, beverage or feed for promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the food, beverage or feed comprises the compound represented by the formula (A) as defined in claim 7, a derivative thereof or a salt thereof, and neither Group III nor Group IV require the particulars of Group I since Group I requires an effective ingredient a processed product derived from a plant selected from the following (a) to (c): (a) a processed product derived from a plant belonging to Umbelliferae; (b) a processed product derived from a plant belonging to Liliaceae; and (c) a processed product derived from a plant belonging to Compositae, whereas Groups III and IV require a compound represented by the following formula (A): a derivative thereof or a salt thereof and a search for a plant

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product is not co-extensive with a search for a compound represented by the following formula (A): a derivative thereof or a salt thereof. The special technical feature of Groups V and IV are drawn to unrelated methods of use, where in the special technical feature of Group V is drawn to a method for measuring an enhancing action for bone morphogenetic protein production, characterized in that the method comprises the following steps of: (a) culturing hybridoma obtained by using HuO9 cells or a substrain thereof, or any one of cell strains therefrom with contact of a test substance; and (b) measuring an amount of BMP in a culture medium obtained in the step (a) as an index for an enhancing action for BMP production of the test substance and the special technical feature of Group VI is drawn to a method for measuring an enhancing action for bone morphogenetic protein production, characterized in that the method comprises the following steps of: (a) culturing hybridoma obtained by using HuO9 cells or a substrain thereof, or any one of cell strains therefrom with contact of a test substance; and (b) measuring an amount of BMP in a culture medium obtained in the step (a) as an index for an enhancing action for BMP production of the test substance. A search for the special technical feature of Group I is not required for a search for the special technical feature of Groups V and VI, since the inventions are unrelated. Finally, the special technical feature of Groups VII and VIII are drawn to method of preparing a substance having enhancing action and a search for the special technical feature of Group I is not required for Groups VII and VIII since the methods of Groups VII and VIII are unrelated to the agent of Group I. Finally, Claim 1, at least, is anticipated by or obvious over Ishino et al. (JP 11-269044, 05.10.1999). Ishino teaches a therapeutic

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agent consisting of an extract of *Compositae gnaphalium*. It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims. Consequently, the special technical feature which links the claims does not provide a contribution over the prior art, so the invention lacks unity.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group I:

Specie A: elect one plant from Claims 1 and 3.

Further elect the corresponding specific plant specie from Claims 2 and 4 that is specific to the elected plant family from Claim 1. For example, if Umbelliferae is elected as Specie A, further elect *Angelica keiskei koidz.* as the plant from Claim 2.

Group II:

Specie A: elect the compound, derivative or salt from Claim 7.

Group III:

Specie A: elect the compound, derivative or salt from Claim 9.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Group I:

- Specie A: drawn to Claims 2 and 4.
- Group II:
 - Specie A: drawn to Claim 6.
- Group III:
 - Specie A: drawn to Claim 8.
- Group IV:
 - Specie A: drawn to Claim 9.

The following claims are generic: Claims 1, 3 and 5.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are independent or distinct because the plant families listed in Claims 1, 3 and 5, the plant species listed in Claims 2, 4 and 6 and the compound, derivatives of the compound and salts of the compound listed Claim 7 are distinct both physically and functionally from each other both within each Claim and between the Claims. And a search for one plant family, one plant specie and a compound is not co-extensive with a search for another.

In response to Applicant's argument that the invention is improperly divided into eight groups and that at least the claims of Groups III and IV should be joined because these Groups each relate to a single general inventive concept under PCT Rule 13.1 due to the fact that under PCT Rule 13.2 they each share the same corresponding special technical feature, that a "special technical feature" is one that defines a contribution that the invention makes over the prior art, that the special technical feature shared among Groups III and IV is 'a compound represented by Formula A', that this feature is sufficient to confer unity of invention to Groups III and IV in the present application, and that the Examiner has put forward no prior art that removes this feature

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of the invention from consideration as a special technical feature and, therefore, claims 7-8 and 9, at least, should be joined, please note the following.

MPEP § 1850 (I and II) states:

“Any international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (PCT Article 3(4)(iii) and 17(3)(a), PCT Rule 3.1, and 37 CFR 1.475). Observance of this requirement is checked by the International Searching Authority and may be relevant in the national (or regional) phase (See *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 650 F. Supp. 218, 231 USPQ 590 (E.D. Va. 1986)) ...

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

Whether or not any particular technical feature makes a “contribution” over the prior art, and therefore constitutes a “special technical feature,” should be considered with respect to novelty and inventive step. For example, a document discovered in the international search shows that there is a presumption of lack of novelty or inventive step in a main claim, so that there may be no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept...”

Applicant’s claimed invention lacks unity for the reasons set forth above.

Furthermore, there is no special technical feature shared between Groups III and IV.

Group III is drawn to “a therapeutic agent or prophylactic agent for a disease requiring promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the therapeutic agent or prophylactic agent comprises as an

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effective ingredient a compound represented by the following formula (A): a derivative thereof or a salt thereof" and Group IV is drawn to "a food, beverage or feed for promotion of osteogenesis or enhancement of bone morphogenetic protein production, characterized in that the food, beverage or feed comprises the compound represented by the formula (A) as defined in claim 7, a derivative thereof or a salt thereof". Please note that no prior art is required to show lack of unity of this invention because these inventions differ from the main invention listed in Group I, which the Examiner applied art to, in order to show lack of unity amongst the related inventions. Since there is no corresponding technical feature between the compound listed in Group III or the compound listed in Group IV, no art is required to show a lack of unity. Furthermore, a search for a therapeutic agent is not co-extensive with a search for a food, beverage or feed, therefore, the restriction is deemed proper and maintained.

In response to Applicant's argument that at least the claims of Groups V, VI, VII and VIII should be joined because these Groups share a special technical feature, i.e. 'culturing hybridoma obtained by using HuO9 cells or a substrain thereof, or any one of cell strains therefrom with contact of a test substance; and measuring an amount of BMP in a culture medium obtained in the step (a)', that this feature is sufficient to confer unity of invention to Groups V, VI, VII and VIII and that this feature makes a contribution over the prior art, please, again refer to MPEP § 1850 (I and II) provided above. Applicant's claimed invention lacks unity for the reasons set forth above. Furthermore, there is no special technical feature shared between Groups V, VI, VII and VIII. Groups V-VIII show unrelated inventions that require different method steps.

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Since these methods require different steps and are, therefore, not related, no art is required to show a lack of unity. Therefore, the restriction is deemed proper and maintained.

Applicant states that the Examiner has required Applicants to elect one species of the invention of Group II, which the Examiner describes as generic and that the Examiner directs Applicants to elect a compound, derivative or salt from claim 7 of Group II (See Office Action, page 7). Applicant further states that claim 7 is not included in Group II and no elected compounds are encompassed within the claims of Group II and, therefore, Applicants assume that they are to elect a plant family and a plant species encompassed by claims 5 and 6 and elect the plant family Umbelliferae and the plant species *Angelica keiskei* koidz and that claims 1-6 read on the elected species. Applicants state that this election of species serves as a starting pointing for search and examination only and that upon indication of allowable subject matter for the elected species, the Examiner must expand the search to include other non-elected species with the intent to finding a generic claim ultimately allowable.

Applicant is correct in the assumption that the Examiner required an election of one plant from Claim 5 and one plant from Claim 6.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-4 and 7-13 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 14 August 2006.

Claims 1-13 are currently pending.

Claims 5 and 6 are under examination.

Information Disclosure Statement

The information disclosure statements (IDS) were filed on 03/31/2005, 03/20/2006 and 04/21/2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

References submitted wherein only the Abstract was in English and where no further translation was provided have the words "Abstract only" written next to the reference, since only the Abstract was considered.

Drawings

The drawings are objected to because the drawings require an appropriate heading. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "A food (beverage, feed) for promotion of osteogenesis comprising (either Family or species of plant)".

The disclosure is objected to because of the following informalities: remove the term "prevention" from paragraphs 0001, 0005, 0009, 0069 and 0139 of the published application, "preventing" from paragraphs 0049 and 0068, "prevented" from paragraphs 0011 and 0049 and "prevent" from paragraph 0066.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 5 are rendered uncertain by the phrase “the food, beverage or feed comprises a processed product derived from a plant” because it is unclear as to what “a processed product derived from a plant” is. “A processed product derived from a plant” could be an extract, a powder, a protein, a bioactive compound, etc. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Okukawa (N, JP 2001-178407, Translation provided herein).

Okukawa teaches a health food that can be drunk as a beverage comprising *Angelica keiskei* powder rich in vitamin K, wherein the food supplies essential vitamins,

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such as D and K, and increases calcium absorption and improves calcium deposition in bones. Please note that calcium is required for healthy bone growth and development, which reads on osteogenesis.

Therefore, the reference anticipates the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Amy L. Clark

September 14, 2006

Michele C. Flood
MICHELE FLOOD
PRIMARY EXAMINER